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Give and Take? Human Bodies in Medicine and Research

Response to Consultation of the Nuffield Council on Bioethics

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The Nuffield Council recently established a Working Party chaired by Prof. Dame Marilyn Strathern to explore the ethical issues raised by the provision of bodily material for medical treatment and research. Broad questions to be addressed include:

- What motivates people to provide bodily material and what inducements or incentives are appropriate?
- What constitutes valid consent?
- What future ownership or control people should have over donated materials?
- Are there ethical limits on how we try to meet (organ and tissue) demand?

The Working Group met for the first time in January 2010. A Consultation Paper was released in April 2010.¹ The consultation closes on 13 July 2010. A report outlining the Working Group's findings, including recommendations for policy, is to be published in autumn 2011.

The following represents a Response to the Consultation. Registered in April 2010, the Response engages with just some of the themes articulated and questions posed in the Consultation Paper. In particular, it addresses the questions of core values and possible governance structures applicable to the tissue and organ procurement setting. The views expressed herein reflect the author's personal opinions, and do not necessarily reflect any wider views or opinions of colleagues in SCRIPT or Innogen, the School of Law, or the University of Edinburgh.

1. Nature of Human Bodily Material and First-in-Human Trials

No response.

2. Purposes of Providing Bodily Material/Volunteering in a Trial

No response.

3. Ethical Values at Stake

Q10: How should these values be prioritised or balanced against each other? Is there one value that should always take precedence over others?

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¹ Nuffield Council, *Give and Take? Human Bodies in Medicine and Research* (London: Nuffield Council, April 2010), available at http://www.nuffieldbioethics.org/fileLibrary/pdf/Human_bodies_in_medicine_and_research_consultation_paper.pdf [accessed 21 April 2010].

While all of these values – altruism, autonomy, dignity, justice, welfare-maximisation, reciprocity, and solidarity – are essential for the operation of a moral and rights-conscious society (ie: a society striving to be a civil society), certain values are currently under-vindicated, not only in this setting but more broadly, and their better promotion and realisation would benefit society, patients and public health. In particular, solidarity is very important and all too often given rhetorical recognition without any real practical weight. Solidarity recognises our interconnectedness, the natural compassion that everyone feels (or should feel) toward others in view of the hardships and misfortunes of those others, and it is in compliance with noble values of dignity, respect and mutual help. It emphasises community and mutual obligations. Legislators and ethics committees and stakeholders in the public health and organ transplantation setting ought to give much more thought and weight to this value and the creativity that it undergirds when it comes to responding to public needs.

Q12: Can there be a moral duty to provide human body material, either during life or after death?

Based on the response to Q10, I feel that a duty to provide body material, certainly after death, may well be morally defended, and grounded in values such as solidarity, reciprocity, welfare-maximisation, justice, and the dignity of the vulnerable or needy (ie: the patient).

4. Responding to Demand

Q14: Is it right always to try to meet demand? Are some ‘needs’ or ‘demands’ more pressing than others?

Conditions resulting in organ degradation and failure (and concomitant transplantation needs) are serious burdens on public health systems, on families, and indeed on ailing patients. Given scarce resources, rising populations, and increasing environmental degradation, it is probably not morally necessary to meet every demand. Rather, life-saving, life-prolonging, and life-enhancing uses are more pressing than life-creating, for they have greater potential to increase public health and ease health resource pressures. Our greater moral responsibility is to ease suffering, facilitate (productive) functionality, and improve human wellbeing.

Having made this distinction, however, the framing of the issue is of great importance. It is preferable to start from the premise that transplantation, as a proven and cost-effective treatment option where it has been sufficiently developed,² is (or should be) a favoured healthcare response to a variety of chronic and otherwise terminal conditions. Used maximally, it could improve the health, functionality, productivity, and enjoyment of life of millions of people, and in doing so, could have a transformative effect on healthcare delivery and healthcare system efficiency.

One might characterise the chronic shortage of transplantable organs and tissue as a purely social problem, but it is appropriate to characterise it as an acute moral issue;

² Numerous studies have demonstrated that kidney transplantation is cheaper than, and improves longevity over, dialysis, as is the case with other forms of transplantation, such as liver and heart: see W. Winkelmayer et al., ‘Health Economic Evaluations: The Special Case of End-Stage Renal Disease Treatment’ (2002) 22 *Med Decision Making* 417-430, R. Adam et al., ‘Evolution of Liver Transplantation in Europe’ (2003) 9 *Liver Transplant* 1231-1243, D. Taylor et al., ‘2006 Report of the International Society for Heart and Lung Transplantation’ (2006) 25 *J Heart Lung transplant* 869-879, and others.

an unethical and unjust state of affairs that represents a fatal shortcoming of the healthcare system as it currently exists.³ By framing the issue as a pressing moral matter, one strengthens the imperative to remedy it, and expands the range of possible (defensible) mechanisms for doing so, the ultimate aim being to promote human wellbeing.

Q15: Should different forms of incentive, compensation or recognition be used to encourage people to provide different forms of bodily material?

Absolutely. The only way to maximise transplant programmes and maximally benefit public health is to adopt a multi-pronged, joined-up approach which more effectively and creatively links social/moral values, legal principles, and regulatory responses to particular medical problems, finding those areas of value convergence and adopting policy positions that vindicate those values while solving the particular (medical) problem to be addressed. Obviously, this represents an impressive but not insurmountable policy-making challenge. Such an integrated approach to organ/tissue procurement might properly include the following 5 components:

1. ***Healthcare Professional Education:*** We must avoid poor or incomplete understanding of the costs, benefits, risks, and long-term consequences of transplantation for patients and for public health. In addition to an increased focus on transplantation as a part of general medical education, all practicing physicians and nurses, especially those working in ICUs, Emergency Units, and Palliative Care Units,⁴ should undergo mandatory continuing professional development training (in person and virtual/online) relating to transplantation. In addition to being informed about the value of transplantation and its importance to public health and national goals, training should focus on donor identification (which must occur early), donor screening (so disease transmission or infection are minimised), donor maintenance (so that organs are obtained in a usable state), sensitive physician-patient/family interaction (so a facilitative environment is created and information can be better shared and assimilated), and organ retrieval (best practices for removing, handling, preserving/storing, and transporting organs).
2. ***Public Education/Promotion:*** Multi-media public education and promotional campaigns, both national and regional,⁵ should be undertaken on an ongoing or rolling basis. A general campaign, realised through print, radio, television, and web media, could advance the following concepts and messages:
 - every individual bears duties grounded in solidarity and altruism to others in society and to the state;

³ Its moral foundation has also been recognized by others: see F. Cantarovich, 'Reducing the Organ Shortage by Education and by Fostering a Sense of Social Responsibility' (2003) 35 Transplantation Proceedings 1153-1155.

⁴ For more on the value of 'marginal donors' like the elderly, minors, diabetics, those with ischemia or infection, and so on, see G. Abouna, 'Organ Shortage Crisis: Problems and Possible Solutions' (2008) 40 Transplantation Proceedings 34-38.

⁵ Such a 2-tiered approach is necessary so that nuances in local character and local reasons for suboptimal donation can be addressed, whether they are socio-cultural, religious, or otherwise: see S. Rizvi et al., 'Improving Kidney and Live Donation Rates in Asia: Living Donation' (2004) 36 Transplantation Proceedings 1894-1895.

- duties extend to obligations to contribute to personal and public health and to the wellbeing of others, thereby improving national productivity;
- transplantation is an important and integral part of effective modern healthcare and is contrary neither to any major religion, nor to traditional ethics;
- every member of society is a potential donor and recipient (ie appeals to enlightened self-interest might highlight that the sharing of a personal resource, either during their life or after death or both, that is unique, may also benefit them in their lives);
- clinical and social outcomes consequent to successful transplantations are typically favourable (and specific evidence might be provided);
- the state and medical institutions are concerned with patient and public health, and risks to participants will always be minimised through strict safety measures and oversight.

This general campaign should be supplemented by campaigns targeting specific audiences. In particular, young people should be reached and encouraged so that health solidarity and transplantation/donation become a part of the national social fabric.

3. ***Transplant Coordination Service:*** A national Transplant Coordination Service (TCS), organised into central and local/institutional branches, should be created so that trained and motivated transplantation experts could manage and advance transplantation medicine. The central/national Secretariat could:

- serve as the interface between the national government and the transplantation community and set broad/national transplantation policy (including conducting public engagement exercises);
- erect and keep current national technical standards (through the hosting of expert consensus conferences);
- undertake oversight and enforcement operations (certifying professionals, licensing hospitals, recertifying through site and records inspections, auditing institutions and practitioners for compliance with ethical allocation practices, generally ensuring compliance with the statutory scheme);
- undertake the proposed professional education and public promotion campaigns, bringing its unique perspective and evidence to bear (and it might provide a 24-hour transplantation telephone hotline for those seeking information⁶); and

⁶ Such a hotline has proved a very useful resource in Spain: see R. Matesanz & B. Dominguez-Gil, 'Strategies to Optimize Deceased Organ Donation' (2007) 21 Transplantation Reviews 177-188.

- facilitate (and coordinate) equitable organ sharing between institutions and across borders.

The local/institutional branches of the TCS would comprise individual Transplant Coordinators (ie: physicians and nurses acting on a part-time basis outside of their medical duties and reporting to the central authority). Transplant Coordinators, rather than treating physicians or nurses, could:

- continuously monitor potential donors;
- approach patients and families about donation and transplantation;⁷
- provide information to individuals, assist in patient identification, articulate and resolve potential conflicts between being a patient and a potential donor;
- obtain consent (where applicable);
- coordinate the various actors involved in performing transplantations, and ensure the provision of adequate follow-up to both recipient and donor (if living) or family (if cadaveric).

A TCS would go a long way toward educating and obtaining evidence from the public, thereby permitting better, evidence-based policies in the future. Through its monitoring and enforcement of transplant standards, a TCS would enhance patient safety, a value already explicitly considered of vital importance. It would also make transplant medicine more transparent and responsive, and therefore more democratic.

4. ***Opt-Out System (Cadaveric Donation):*** A nation-wide opt-out system for cadaveric donation should be instituted whereby every member of society is automatically a contributor to transplant medicine.⁸ Thus, unless one specifically opts-out via a written form provided to a TCS coordinator and entered onto a central registry maintained by the TCS, one is automatically a member of the donation scheme such that when one dies, either naturally or by an accident, any organs and tissue of suitable quality are made available to patients within that region. Those who opt out would be issued an opt-out card to be carried on their person. While some will complain that an opt-out approach diminishes, or is incompatible with, autonomy, in fact, it preserves autonomy and respect for the person insofar as every individual has the right, at any time, and after the consideration of as much or as little information as desired, to make an 'informed choice', to express that choice, and to have both respected. Ultimately, it strikes a reasonable balance between individual choice and promotion of the public

⁷ It has been reported that the Hong Kong Transplant Coordination Service, established in 1988, has enjoyed great success, raising the procurement rate from 10% to 40%: T. Chan, 'Donor Shortage in Organ Transplantation: Perspectives from Hong Kong' (2002) 34 *Transplantation Proceedings* 2558-2559.

⁸ This is sometimes called 'presumed consent'. I prefer not to use 'presumed consent' because this is an unhelpful fiction; we are not presuming consent, we are disposing of the need for consent, and extending to individuals and families the possibility of exercising 'informed refusal' through the act of withdrawal.

good. It is impossible to say who might object to an opt-out approach; this is an area which demands greater empirical work.⁹

5. ***Rewarded Donation System (Living Donation):*** It is fair to characterise live organ/tissue donation as an intimate form of social interaction which should result in some form of reciprocity.¹⁰ In short, some benefits should be enjoyed by all participants (eg the public, the recipient, and the donor), and this seems to be the most fair and equitable approach (much more so than purely altruistic donation, which has proven wholly incapable of meeting demand).¹¹ While it has been claimed that the near universal rejection of a commercialised organ trade is gradually eroding,¹² it remains a controversial and, to many, an unpalatable option for increasing procurement rates.¹³ As such – and given the existing international rejection of organ markets,¹⁴ as well as the touchstones of duty, solidarity, and rewarded altruism – a non-market approach to living donation is favoured. Survey evidence suggests that some recognition is warranted. This recognition could come in several forms, some of them compensatory, and it might include the following:

- *Social Recognition:* While one might hope for donation decisions to be purely solidaristic, it is not necessary to demand unbridled altruism of people, and its absence need not taint the act. Recognition might take several forms, from letters of appreciation from government and/or recipient (anonymised or not), to certificates of special recognition from the government and/or health authorities, to inclusion on a publicly searchable national list of live donors (for those wishing to waive their privacy rights).
- *Enhanced Organ/Tissue Eligibility:* Live donors, or a designated member of their immediate family, might automatically become eligible for ‘enhanced consideration’ should they develop a need for a transplantable organ or tissue. Their particulars could be entered onto national and regional registries until such time as they might have to enter a waiting list for a specific transplant, at which time they would be ranked as if they had been entered on the date of their donation.

⁹ Many countries have adopted opt-out schemes, including Austria, Belgium, Spain, and Sweden, with varying degrees of success.

¹⁰ M. Schweda & S. Schicktanz, ‘Public Ideas and Values Concerning the Commercialization of Organ Donation in Four European Countries’ (2008) 68 Soc. Sci. Med. 1129-1136.

¹¹ In fact, demands for improved social recognition of donors is not new: see R. Veatch, ‘Routine Inquiry About Organ Donation: An Alternative to Presumed Consented’ (1991) 325 New Eng J Med 1246-1249.

¹² M. Schweda & S. Schicktanz, note 10. Iran permits organ sales: see A. Daar, ‘The Case for a Regulated System of Living Kidney Sales’ (2006) 2 Nature Clin. Nephrology 600-601. And see C. Erin & J. Harris, ‘An Ethical Market in Human Organs’ (2003) 29 JME 137-138, who advocate a brokered market approach.

¹³ See these studies: M. Schweda & S. Schicktanz, note 10, and C. Mehmet et al., ‘How to Improve Organ Donation: Results of the ISHLT/FACT Poll’ (2003) 22 J Heart Lung Transplant 389-410.

¹⁴ See Principles 5 and 6 of the *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, Document EB123/5, WHO Executive Board, 26 May 2008.

- *Improved Health Insurance Coverage:* Live donors, or a designated member of their immediate family, might automatically become eligible for improved health insurance.
- *Related Expenses:* Live donors should receive financial compensation in the form of paid travel (and, if necessary, hotel) expenses for pre-op testing and post-op follow-up visits to the hospital, paid nutrition allowances for days spent travelling, wage continuation coverage for the duration of their convalescence, and a nominal, legislatively set financial award for the pain and inconvenience they will suffer as a result of surgery. This compensation might be contributed to by the state and by the private insurers of employers and hospitals.

This multiple reward system, built into the law, could reverse trends with respect to availability of quality transplantable organs from living donors (which are the best organs and the most likely to result in success and long-term health outcomes).¹⁵

It is important to note that no singular approach is likely to have any significant impact with respect to reversing current trends. Further, and importantly, there is very little evidence for claiming that any one of the above strategies will work. However, combined, they should have palpable positive effects. Social research in this area would be useful.

5. The Role of Consent

Q25: What part should family members play in deciding whether bodily material may be used after death (a) where the deceased person's wishes are known, and (b) where they are unknown? Should family members have any right of veto.

This is a very sensitive issue, and one which places healthcareers in a difficult position. Clarity in the law might assist them. Obviously, families should (and do) play a part in these decisions. However, where the deceased person's wishes are known (eg: contained in an Advanced Directive or Will), the family should have no veto, unless there is highly persuasive evidence that the deceased person's wishes have changed from those contained in the legal instrument. Where the deceased person's wishes are unknown, the position of the family (assuming it is unified) might have greater weight, but if it is divided, public authorities should empower healthcareers to presume consent for this will ultimately benefit public health and vindicate a range of values.

6. Ownership and Control

Q26: To whom, if anyone, should a dead body or its parts belong?

This is a difficult question which probably deserves empirical research. There is some justification for adopting the position that the dead body (and its parts) are public goods and part of the person's 'giving back' to society and comporting to solidarity. This may be justified where the body (or its parts) are destined to serve patients and public health

¹⁵ See G. Abouna *et al.*, 'The Living Unrelated Donor: A Viable Alternative for Renal Transplantation' (1988) 20 *Transplantation Proceedings* 802-804, and more.

directly, but probably less so where it is desired for research by private or profit-oriented entities.

7. Any Other Issues

Q30: Are there any other issues, connected with our Terms of Reference, that you would like to draw to our attention?

While it is important to recognise that the UK is a heterogeneous multicultural society, one might note that emerging empirical data in jurisdictions that have traditionally been wary of donation (particularly cadaveric donation) and transplantation suggests that people support this element of public health. One example is China (from which the UK receives a lot of immigrants). A variety of large surveys conducted in Hong Kong and mainland China expose a commonly shared concern for, or 'solidarity' with, other humans; certainly family members, but also other vulnerable people or groups.¹⁶

¹⁶ See T. Chan, note 7, B. Cheng et al., 'An Overview of Attitudes Towards Organ Donation in Hong Kong' (2005) 7 HK J Nephrol 77-81, Y-F. Tong et al., 'Needs and Experiences of Hong Kong Chinese Cadaveric Organ Donor Families' (2006) 8 HK J Nephrol 24-32, L. Zhang et al., 'Knowledge and Willingness Toward Living Organ Donation: A Survey of Three Universities in Changsha, Hunan Province, China' (2007) 39 Transplantation Proceedings 1303-1309.